Alabama Medicaid Agency

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BOB RILEY
Governor

CAROL H. STECKEL, MPH
Commissioner

July 25, 2008

Dear Pharmaceutical Manufacturer:

This correspondence is to provide you with formal written notification of an upcoming meeting of the Alabama Medicaid Pharmacy & Therapeutics (P&T) Committee, to be held on **Wednesday, September 10, 2008**. This meeting may involve review of one or more of your company's drug products. Please note: this meeting will be held at the Alabama State Capitol Auditorium located in Montgomery, Alabama, and will begin at 9:00 a.m. All meetings of this committee are open to the public.

The following is a list of drug classes for review at this meeting:

Drug Class REVIEWS	
1. Central α-Agonists – AHFS 240816	9. Angiotensin-Converting Enzyme Inhibitors – AHFS 243204
2. Direct Vasodilators – AHFS 240820	10. Angiotensin II Receptor Antagonists – AHFS 243208
3. Peripheral Adrenergic Inhibitors – AHFS 240832	11. Mineralocorticoid (Aldosterone) Receptor Antagonists – AHFS 243220
4. Miscellaneous Hypotensive Agents – AHFS 240892	12. Renin Inhibitors – AHFS 243240
5. α-Adrenergic Blocking Agents – AHFS 242000	13. Loop Diuretics – AHFS 402808
6. β-Adrenergic Blocking Agents – AHFS 242400	14. Potassium-sparing Diuretics – AHFS 402816
7. Dihydropyridines – AHFS 242808	15. Thiazide Diuretics – AHFS 402820
8. Miscellaneous Calcium-Channel Blocking Agents – AHFS 242892	16. Thiazide-like Diuretics – AHFS 402824

** Please note that a new drug product must be on the market for a minimum of 6 months from launch date in order to be included in a drug class review.*

As you may be aware, manufacturers whose products are scheduled for review are allowed the opportunity to provide written clinical comments for distribution to the Medicaid P&T Committee members prior to the meeting. For products slated for P&T Committee review, manufacturers are also allowed the opportunity to make brief (no more than 5 minutes) oral summary presentations of their products' clinical data to the Medicaid P&T Committee on the day of the meeting. At the initiation of the 5 minute presentation, the speaker will be required to state any financial interest in or other relationship with the manufacturer of any product(s) the speaker intends to discuss.

Approval for distribution of written clinical comments to P&T Committee members and approval of oral presentation summary submissions are based strictly upon the following guidelines:

Written Comments:

1) All written comments must be mailed to Medicaid's Clinical Contractor, *Goold Health Systems (GHS) – Clinical Pharmacy Services, Attn: AL Medicaid P&T Support (1-800-832-9672); P.O. Box 1090; Augusta, ME 04332*, and received no later than **Wednesday, August 20, 2008**. Packages must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information of the designated manufacturer's point of contact.

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2) Submissions should be limited to one drug product per packet. Manufacturers wishing to provide written comments on more than one drug product must submit a separate packet for each product.
3) **Submissions are limited to 100 pages single-sided (or 50 pages double-sided) and a maximum binder size of 1 inch.**
4) Written comments should be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
5) Written comments must be confined to evidence-based clinical information and limited to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content.
6) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.).
7) Manufacturers must provide **twenty (20) copies of written comments** upon submission to *GHS at the above mentioned contact information.*

Oral Presentation Summaries:

1) Written notification of your intent to make an oral presentation must be mailed to *Goold Health Systems (GHS) – Clinical Pharmacy Services, Attn: AL Medicaid P&T Support (1-800-832-9672); P.O. Box 1090; Augusta, ME 04332*, and received no later than **Wednesday, August 20, 2008**. Submissions must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information of the designated manufacturer's point of contact.
2) Oral presentation summaries should be limited to one drug product per submission. Manufacturers wishing to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.
3) Oral presentations must also be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
4) Oral presentations must be confined to evidence-based clinical information and limited to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference form.
5) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.) and should be clearly labeled as "Oral Presentation Summary".
6) **One (1) copy of a one-page summary** of the material to be presented must be received along with the written notification. (Please note: the presentation summary must be a single-sided document; references, package inserts, and any other information may be submitted but only the summary will be reviewed).

Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments and/or oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline.

Please refer to the Medicaid website for additional information related to presentations, timelines, clinical comment submissions, and/or submission of volume discounts. Volume discount submissions should not be included in this submission to GHS, as these will not be reviewed by GHS nor forwarded to Alabama Medicaid. If you should have additional questions regarding this notice or if you have received this letter and are no longer the appropriate contact, please notify the Medicaid Pharmacy Program at (334) 353-4582.

Sincerely,

Bakeba R. Thomas

Bakeba R. Thomas, Administrator
Pharmacy Clinical Support Unit